

### 510(k) Summary

JUL - 2 2007

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR \$\qquad 807.92(a).

### 807.92(a)(1)

### **Submitter Information**

Carri Graham, Official Correspondent 11460 N. Meridian St., Suite 150 Carmel, IN 46032

Phone:

(317) 569-9500, extension 103

Facsimile:

(317) 569-9520

Contact Person:

Carri Graham

Date:

March 20, 2007

### 807.92(a)(2)

Trade Name:

MyLab40 Ultrasound System

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulsed echo imaging system

892.1560 em 832.1550

Ultrasonic pulsed Doppler imaging system
Diagnostic ultrasonic transducer

892,1570

Classification Number:

IYO

IYN

ITX

510(k) Summary MyLab40 Esaote Europe

### 807.92(a)(3)

### Predicate Device(s)

Pie Medical	MyLab20	K043588
Pie Medical	MyLab20	K053154
Esaote Europe	MyLab20	K061755
Esaote S.p.A.	MyLab30	K040596
Esaote S.p.A.	MyLab30	K052805
Esaote S.p.A.	MyLab30	K060827

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

### 807.92(a)(4)

### **Device Description**

The MyLab40 is a compact console ultrasound system used to perform general diagnostic ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler, 3D/4D, Color Flow Mapping and on lower frequency probes, Tissue Enhancement Imaging (TEI). The system is equipped with a LCD color display and can drive Phased Array (PA), Convex Array (CA), Linear Array (LA) and Doppler probes. The MyLab40 is able to produce Real Time 2D images and 3D images in manual mode with all probes. The system in combination with the BC431 or BS230 probe, offer the possibility to also produce automatic 3D and Real Time 4D images. The MyLab40 is manufactured under an ISO9001:2000 and ISO13485:2003 certified quality system.

### 807.92(a)(5)

### Intended Use(s)

The MyLab40 is a compact console ultrasound system used to perform general diagnostic ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organ, Musculoskeletal (Conventional & Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic.

### 807.92(a)(6)

### **Technological Characteristics**

ESAOTE believes that the MyLab40 is substantially equivalent to the Esaote's MyLab20 product (K043588, K053154 and K061755) and the Esaote's MyLab30 product (K040596, K052805 and K060827).

	MyLab40 To be cleared via this submission	MyLab30 K040596 K052805* K060827**	MyLab20 K043588 K053154*** K061755****
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic
Indication for Use:	Output Display)	Output Display)	Output Display)
Cardiac	YES	YES	YES
Transesophageal	YES	YES	NO
Peripheral Vascular	YES	YES	YES
Neonatal Cephalic	YES	YES	YES
	YES		
Adult Cephalic		YES	NO
Small organ	YES	YES	YES
Musculoskeletal     (conventional & superficial)	YES	YES	YES
<ul> <li>Abdominal</li> </ul>	YES	YES	YES
OB/Fetal	YES	YES	YES
Transvaginal	YES	YES	YES
Transrectal	YES	YES	YES
Pediatric	YES	YES	YES
Intraoperative:     Abdominal	YES	YES*	YES****
Other: Urological	YES	YES**	YES****
Probe Technology			
Annular Array	NO	NO	NO
Phased Array	YES	YES	NO
Linear array	YES	YES	YES
Convex Array	YES	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI, 3D/4D	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI, 3D/4D**	2D, M-Mode, PW, CFM, Amplitude Doppler, TEI, 3D/4D***
Additional Modes of operation:		JUITO	UPIN
Compound Imaging	YES	YES**	No
• CMM	YES	YES**	No
• VPAN	YES	YES**	No
• CnTI	YES	YES**	No
Strain Rate Quantification	YES	YES**	No

Esacte Lurope	MyLab40	MyLab30	MyLab20
	To be cleared via this	1 ~	K043588
·	submission	K052805*	K053154***
	3401111331011	K060827**	K061755****
• TVM	YES	YES**	No No
Imaging Frequencies	2.0 - 16 MHz	2.0 - 16 MHz	2.7 - 15 MHz
CFM/Doppler Frequencies	2.0, 2.5, 3.3, 5.0, 6.6,	2.0, 2.5, 3.3, 5.0, 6.6,	2.7, 3.5, 5.0, 6.3 MHz
	8.0 MHz	8.0 MHz	
Tissue Velocity Mapping feature	YES	YES	NO
Biopsy Guidance	YES	YES	YES
Biopsy Intended Uses	General Purpose,	General Purpose,	General Purpose,
	Transrectal,	Transrectal,	Transrectal,
	Transvaginal	Transvaginal	Transvaginal
Biopsy Line Depth marker	1 cm	1 cm	1 cm
Needle Guide Angle	ABS421: 20° 30°	ABS421: 20° 30°	ABS421: 20° 30°
	ABS523: 45°	ABS523: 45°	ABS523: 45°
	ABS123: 3.8°	ABS123: 3.8°	ABS123: 3.8°
1	ABS621: 25° 35°	ABS621: 25° 35°	ABS621: 25° 35°
	ABS424: 45°	AB\$424: 45°	ABS424: 45°
	BS230KIT: 12.5° 20°	BS230KIT: 12.5° 20°	ABS15: 45°
	ABS15: 45°	ABS15: 45°	
Display Type	SVGA	SVGA	SVGA
Monitor	LCD	LCD	LCD CRT
Digital Archival	YES	YES	YES
Capabilities			
DICOM Classes:			
Image Storage	YES	YES	NO
Multiframe Image	YES	YES	NO
Storage		1135	
· · · · · · · · · · · · · · · · · · ·	YES	VEC	NO
Basic Grayscale Print	1123	YES	NO
Management	T.T.O.	1 TEO	210
Basic Color Print	YES	YES	NO
Management			
Secondary Capture	YES	YES	NO
Image Storage			
Modality Worklist	YES	YES	NO
Storage Commitment	YES	YES	NO
Push Model			
Modality Performed	YES	YES	NO
Procedure Step	. 20		
VCR / Page Printer	YES	VEC	VEC
	1 E 5	YES	YES
M&A Capabilities	Cardiac, Vascular,	Cardiac, Vascular,	Cardiac, Vascular,
<b>,</b>	OB, GYN and general	OB, GYN and general	OB, GYN and general
	purpose measurements	purpose measurements	

510(k) Summary MyLab40 Esaote Europe

	MyLab40 To be cleared via this submission	MyLab30 K040596 K052805* K060827**	MyLab20 K043588 K053154*** K061755****
Weight	60 kg (excl. monitor)	10 kg	60 kg (excl. monitor)
Dimensions	135 (H) x 54 (W) x 80 (D) cm	portable position: 35.5 (w) x 14 (h) x 49 (d) cm use position: 35.5 (w) x 41 (h) x 49 (d) cm	135 (H) x 54 (W) x 80 (D) cm



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL - 2 2007

Esaote Europe B.V. % Ms. Carrie Graham Consultant The Anson Group 11460 N. Meridian St., Ste. 150 CARMEL IN 46032

Re: K070903

Trade Name: MyLab40

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 21, 2007 Received: May 22, 2007

### Dear Ms. Graham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLab40, as described in your premarket notification:

### Transducer Model Number

BC431	<u>LA532E</u>	<u>LA424</u>
BS230	<u>LA435</u>	<u>TEE022</u>
<u>PA230E</u>	<u>CA421</u>	<u>TEE122</u>
<u>PA121E</u>	<u>CA621</u>	<u>IOE323</u>
<u>PA122E</u>	<u>CA631</u>	<u>EC123</u>
<u>PA023E</u>	<u>CA123</u>	2.0 CW Probe
LA523	<u>CA431</u>	5.0 CW Probe
LA522E	CA430E	•

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

### Indications for Use

510(k) Number (if known):	K070903	·		
Device Name:	MyLab40			
Indications For Use:				
Esaote's MyLab40 is a comp general ultrasound studies in Neonatal Cephalic, Adult Ce Superficial), Abdominal, Feta Abdominal and Other: Urolo	ncluding Cardiac, Trans phalic, Small Organ, M al, Transvaginal, Transr	esophageal, Peri usculoskeletal (C	pheral Vascula onventional ar	ar,
Prescription UseX_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Cour (21 CFR 807 Sub		
(PLEASE DO NOT WRITE NEEDED)	E BELOW THIS LINE-C	ONTINUE ON AN	IOTHER PAG	E IF
Concurrence	of CDRH, Office of De	vice Evaluation (0	DDE)	
τ.	Division Sign-Off) Division of Reproductive, About Radiological Devices	dominal,		

### Model 2750 (MyLab40)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<u> </u>	Mode of Operation										
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic	_											
Fetal		N.	· N	N		N	N		N[2]	N[3,4,9]		
Abdominal	<u> </u>	N	N	N	N	N	N		N[2]	N[3,4,5,7,9]		
Intraoperative Abdominal		N.	N	N		N	N		N[2]	N[3,5,7]		
Intraoperative Neurological												
Pediatric		N	N	N	N	N	N		N[2]	M(2.5.0)		
Small Organ (specify) [1]		N	N	N	N	N	N		N[2]	N[3,5,9]		
Neonatal Cephalic		N	N	N	N	N	N		N[2]	N[3,5,7,9] N[3]		
Adult Cephalic		N	N	N	N	N	N		N[2]	N[3]		
Cardiac		N	N	N	N	N			N[2]			
Transesophageal		N	N.	N	N	N	N		N[2]	N[3,4,6,8,9]		
Transrectal	·	N	N ·	N		Ŋ	N			N[3,4,6,8]		
Transvaginal		N	N	N		N	N	****	N[2]	N[3,7,9]		
Transurethral							•		N[2]	N[3,7,9]		
Intravascular		,								·		
Peripheral Vascular		N	N	N	N	N	N		Mol			
Laparoscopic							- 14	· · · · · ·	N[2]	N[3,5,9]		
Musculo-skeletal Conventional		N	N	N	N	N	N		N[2]	N[3,5,9]		
Musculo-skeletal Superficial		N	N	N	N	N	N		N[2]	N[3,5,9]		
Other (Urological)		N	N	N	N	N	N		N[2]	N[3,5,7,9]		

N=new indication; P=previously cleared by FDA; E= added under Appendix E Additional Comments:

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI) Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number\_

	Mode of Operation											
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal		N	N	N		N	Ŋ		N(1)	N[2,3,4,9]		
Abdominal		N	N	N		Ŋ	N		N(1)	N(2,3,4,5,9)		
Intraoperative Abdominal		<u>.</u>				-	· .					
Intraoperative Neurological												
Pediatric		N	N	· <b>N</b>		N	N		N(1)	N(2,3,5,9]		
Small Organ (specify)				1.1								
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal			**									
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular		N	N	N		N	N		N(1)	N(2,3,5,9)		
Laparoscopic												
Muscolo-skeletal Conventional												
Muscolo-skeletal Superficial												
Other (Urological)		N	N	N		N	N		N(1)	N(2,3,5,7,9)		

- [1] Applicable combined modes: B+M+PW+CW+CFM+PD
- [2] Tissue Enhancement Imaging (TEI)
  [3] Compound Imaging
  [4] Compass M-Mode (CMM)

- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO	O NOT WRI	TE BELOW THIS LIN	E. CONTINUE ON ANOTHER PAGE IF NEEDEI	)
- 1			ice of Device Evaluation (QDE)	
		Prescription Use	(Per 21 CFR 801.109)	
			1/ 1/2	
	1.0		della	

Herrem	
(Division Sign-Off)	
Division of Reproductive, Abd	ominal, 2
and Radiological Devices	ノハイハロハス
510(k) Number	10 (0 10)

	Mode of Operation												
Clinical Application	٨	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal										<u>-</u> .			
Abdominal		N	N	N	N	N	N		N[1]	N[2,3,5,7,9]			
Intraoperative Abdominal Intraoperative													
Neurological	ļ	ļ					· · · · · · · · · · · · · · · · · · ·						
Pediatric	<u></u>												
Small Organ (specify)		<u>                                     </u>					*			. · 			
Neonatal Cephalic		ļ											
Adult Cephalic		N	N	N	N	N	N		N[1]	N[2,3]			
Cardiac		N	N	N	N	N	N		N[1]	N[2,3,4,6,8,9]			
Transesophageal									4:				
Transrectal													
Transvaginal									:				
Transurethral		Ī .											
Intravascular	:												
Peripheral Vascular	1												
Laparoscopic					· ·								
Muscolo-skeletal Conventional			1										
Muscolo-skeletal Superficial													
Other (Urological)													

- [1] Applicable combined modes: B+M+PW+CW+CFM+PD
- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO	NOT WRITE	<b>BELOW THIS</b>	LINE. CO	NTINUE ON	ANOTHER	PAGE IF	NEEDED
		rence of CDRH,					**
		Prescription V	Jse (Per 2	1 CFR 801.1	109) /	]	

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_

<u>ろ</u>

### **PA230E**

		Mode of Operation								
Clinical Application	٨	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		N(1)	N[2,3,4,5,7]
Intraoperative Abdominal					·					
Intraoperative Neurological										
Pediatric										
Small Organ (specify)	1									
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N(1)	N[2,3]
Cardiac		N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transesophageal						100				
Transrectal										
Transvaginal										
Transurethral	-									
Intravascular	1						_			
Peripheral Vascular										
Laparoscopic				,						
Muscolo-skeletal Conventional									2.1	
Muscolo-skeletal Superficial										
Other (Urological)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

- [1] Applicable combined modes: B+M+PW+CW+CFM+PD
- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTl
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NO	OT WRITE BELOW THIS LINE. CONTINUE ON A	NOTHER :	PAGE IF	NEEDED
•	concurrence of CDRH, Office of Device Evaluat	tion (ODE)	١	*
	Prescription Use (Per 21 CFR 801.109	9)		

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_

### **PA121E**

				··· <del>··· ·</del> ···		Mode of	Operation			
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal			·							
Abdominal		Ŋ	N	· N	N	N	N		N(1)	N[2,3,4,5,7]
Intraoperative Abdominal										
Intraoperative Neurological								· ·		
Pediatric		1.								·
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic	Ţ									
Cardiac	1	N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transesophageal							- ·			
Transrectal										
Transvaginal			1.					21		
Transurethral									. :	,
Intravascular										·
Peripheral Vascular		N	N	N	N	N	N		N(1)	N[2,3,5]
Laparoscopic							1944 1944 - 1944			
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)						19 400				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

- [1] Applicable combined modes: B+M+PW+CW+CFM+PD
- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] **VPAN**
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number \_\_\_\_

5

### **PA122E**

;	ľ			٠	÷	Mode of	Operation			
Clinical Application	A	В	М	PWD (PW)	(CM)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				•						
Fetal										<u> </u>
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N.		N[1]	N(2,3,5)
Small Organ (specify)										
Neonatal Cephalic		N <sup>i</sup>	N	N	N	N	N		N[1]	N(2,3)
Adult Cephalic							:			
Cardiac		N	N	N	N	N	N		N[1].	N(2,3,4,6,8)
Transesophageal										:
Transrectal							, .			
Transvaginal										
Transurethral										
Intravascular										1, 2 1 2 2 3
Peripheral Vascular	1	N	N	N	N	N	N		N[1]	N(2,3,5)
Laparoscopic			,							
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

- [1] Applicable combined modes: B+M+PW+CW+CFM+PD
- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

### **PA023E**

						Mode of	Operation			<u> </u>
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	1									
Fetal								- 1-1		
Abdominal				7						
Intraoperative Abdominal					<del></del>					
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N(1)	N(2,3,5)
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N(1)	N(2,3)
Adult Cephalic		٠,								
Cardiac		N	N	N	N	N	N		N(1)	N(2,3,4,6,8
Transesophageal										
Transrectal										:
Transvaginal										
Transurethral		2				N.				
Intravascular		41 .	-							
Peripheral Vascular		N	N	N	N	N.	N		N(1)	N(2,3,5)
Laparoscopic										
Muscolo-skeletal Conventional					:					
Muscolo-skeletal Superficial										
Other (Urological)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

- [1] Applicable combined modes: B+M+PW+CW+CFM+PD
- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices 1070903

		Mode of Operation								
Clinical Application	A	В	м	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										i
Fetal										
Abdominal		N	N	N		N	N		N(2)	N[3,4,5,6,8]
Intraoperative Abdominal				:						
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic		N	N	N		N	N		N(2)	N(3,4)
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal			777							
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N(2)	N[3,4,6]
Laparoscopic								1		
Muscolo-skeletal Conventional		N	N	N		N	N	K	N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)										

- [1] Small organs include Thyroid, Breast and Testicles.
   [2] Applicable combined modes: B+M+PW+CW+CFM+PD
   [3] Tissue Enhancement Imaging (TEI)

- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

PLEA	concurre	BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED TICE of CDRH, Office of Device Evaluation (ODE)
2.1 2.		Prescription Use (Per 21 CFR 80), 109
		(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices K07093 8 510(k) Number

### **LA522E**

		Mode of Operation								
Clinical Application	A	В	м	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	, N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal					* .					
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		Ń	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic	1 m								·	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										1 4 4
Intravascular						4.			-	
Peripheral Vascular	7.	N	N	N		N	N	٠.	N[2]	N[3,4,6]
Laparoscopic					4.14.					
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)	. 2									

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)[8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PA	GE IF	NEEDED
concurrence of CDRH, Office of Device Evaluation (ODE)		
Prescription Use (Per 21 CFR 801.109)	/ 1	

(Division Sign-Off)	
Division of Reproductive,	Abdominal,
and Radiological Devices	N 071913
510kl Number	16 / 4 / 1 / / / / / / / / / / / / / / / /

### LA532E

						Mode of	Operation			
Clinical Application	A	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal				_					:	
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal				· · · ·						
Intraoperative Neurological							. /			
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal	1									
Transrectal							5.41 ·			
Transvaginal										
Transurethral										•
Intravascular										1
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic						1 115				
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)										

- [5] C
- [7] Ti [8] Ci

- [9] X: [10] 3

[1] Small organs include Thyroid, Breast and	
[2] Applicable combined modes: B+M+PW+CV	V+CFM+PD
[3] Tissue Enhancement Imaging (TEI)	
[4] Compound Imaging	
[5] Compass M-Mode (CMM)	
[6] VPAN	
[7] Tissue Velocity Mapping (TVM)	
[8] CnTI	
[9] XStrain	
[10] 3D/4D Imaging	
(PLEASE DO NOT WRITE BELOW THIS LINE. (	CONTINUE ON ANOTHER PAGE IF NEEDED
concurrence of CDRH, Office of Prescription Use (Per	
	- Junicana
	(Division/Sign-Off)
	Division of Reproductive, Abdominal,
	and Radiological Devices 17/9/9
	510(k) Number R0 1070 10
	And the second s

		Mode of Operation								
Clinical Application	Α	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N(2)	N[3,4,5,6,8]
Intraoperative Abdominal					·		,			
Intraoperative Neurological								·		
Pediatric		N	N.	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral					-				:	
Intravascular						_				
Peripheral Vascular		N	N	N		N	N		N(2)	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)					1		24.7			:

- [1] Small organs include Thyroid, Breast and Testicles.[2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

concurrence of CDRH, Office of Device Evaluation (QDE)  Prescription Use (Per 21 CFR 801.109)										
		July eum								
		(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices								

510(k) Number \_

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

	Mode of Operation									
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										· · · · ·
Fetal		N	N,	N		N.	N		N[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal						-				
Intraoperative Neurological										
Pediatric	7	N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify)		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic			* .							
Adult Cephalic					* 1					
Cardiac								e .		
Transesophageal		1, 7							-	
Transrectal					7.					
Transvaginal										
Transurethral						·			ji .	
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic						4				
Muscolo-skeletal Conventional		N	N,	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)		N	N	N		N	N	1	N[2]	N[3,4,6,8]

- [1] Small organs include Thyroid, Breast and Testicles.
  [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CON concurrence of CDRH, Office of D Prescription Use (Per 21	evice Evaluation (ODE)
	John Jew
	(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number \_

	Mode of Operation									
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N[2]	N[3,4,5]
Abdominal		N	N	N		N	N	-	N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	. N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N	,	N(2)	N[3,4,6,8]
Neonatal Cephalic			-						7	
Adult Cephalic										
Cardiac										
Transesophageal						1				
Transrectal										
Transvaginal				s V dje i s					. :	
Transurethral						7.7				
Intravascular							·			
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										<u> </u>
Muscolo-skeletal Conventional		N	N	N		N	N	7.3	N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)		N	N	N		N	N		N[2]	N[3,4,6,8]

- [1] Small organs include Thyroid, Breast and Testicles.[2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO NOT	WRITE BELOW THIS LINE.	CONTINUE ON ANG	OTHER PACE	C IE AUGEDED
	concurrence of CDRH, Office	of Device Evaluation	n (ONE)	, IL MEEDED
	Prescription Use (Pe	r 21 CFR 801.699	1000	سستاسف

(Division Sign-Off)			-
Division of Reproductive, A	bdominal	2000	7
and Radiological Devices 510/k) Number	ROI	0903	)

	Mode of Operation									
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic								L		
Fetal		N	N	N		N	N		N[2]	N[3,4,5]
Abdominal		N	N	N		N	N	-	N[2]	N[3,4,5,6,8]
Intraoperative Abdominal Intraoperative										
Neurological	<u> </u>			·					1	
Pediatric		N	N	N		N	N	, -	N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic				·						
Adult Cephalic										
Cardiac										· · · · · ·
Transesophageal									- 1	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic						, .			1.5	
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)		N	N.	N		N	N		N[2]	N[3,4,6,8]

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO 1	NOT WRITE	BELOW THIS LINE. (	CONTINUE ON	ANOTHER PA	&R IF WEEDED	
	concur	rence of CDRH, Office of	of Device Evalu	lation (ODE)		19
<u></u>	:	Prescription Use (Per	21 CFR 601.1	Lycene		
		(E	ivision Sign-	-Off)		
•				productive, A	bdominal,	

510(k) Number

	Mode of Operation									
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic							<del>-</del>			<del>-</del>
Fetal			i				<u> </u>			
Abdominal	1	N	N	N	-	N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal				<del>-</del>					[-]	11[0] 1,0,0,0
Intraoperative Neurological				-						
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic		N	N	N		N	N .		N[2]	N[3,4]
Adult Cephalic										
Cardiac		N <sub>.</sub>	N	N		N	N		N[2]	N[3,4,5,7,9]
Transesophageal			-							[-,,-,-,-,-]
Transrectal							· · · · · · · · · · · · · · · · · · ·			
Transvaginal		·- <u>-</u> -	· -							
Transurethral										· · · · · · · · · · · · · · · · · · ·
Intravascular										
Peripheral Vascular		N	N	N		N	N N		N[2]	N[3,4,6]
Laparoscopic									(2)	
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)				11					- -	

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO NOT	concurrence of CDRH, Office of Device Evaluation (ODE)  Prescription Use (Per 21 CFR 801, 109)
	Julyten
	(Division Sign-Off)
•	Division of Reproductive, Abdominal,

and Radiological Devices 1070903

	Mode of Operation									
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	:	N[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal								-		<u> </u>
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										:
Transurethral									· · · · · · · · ·	
Intravascular										
Peripheral Vascular		Ŋ	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic							·			
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	И , , ,		N[2]	N[3,4,6]
Other (Urological)		N	N	N		N.	N	t en la la	N[2]	N[3,4,6,8]

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTl
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)	
Division of Reproductive.	Abdominal
and Radiological Devices	NO70903
510(k) Number	- KU 10700

16

### **CA430E**

	Mode of Operation									
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N.	N		N	N		N[2]	N[3,4,5]
Abdominal		N	N	N		Ŋ	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										[0,1,0,0,0]
Intraoperative Neurological										
Pediatric				<del></del>						· · · · · · · · · · · · · · · · · · ·
Small Organ (specify)		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic								1		
Adult Cephalic										!
Cardiac										
Transesophageal										
Transrectal								i		
Transvaginal									<u> </u>	
Transurethral										
Intravascular										<u> </u>
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic	7									- [-, ,,-]
Muscolo-skeletal Conventional		N.	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)		N	N	N		N	N		N(2)	N[3,4,6,8]

- [1] Small organs include Thyroid, Breast and Testicles.
  [2] Applicable combined modes: B+M+PW+CW+CFM+PD
  [3] Tissue Enhancement Imaging (TEI)

- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

ADT EAST DO NO	<del></del>				
LEFFUSE DO MO	T WRITE BELOW THIS LIN	E. CONTINUE O	N ANOTHED	PAGE TE	MEEDED
	concurrence of CDRH, Off	ion of Down		I AGE IF	MEEDED
	concerned of CDKH, Off	ice of Delibe EAS	ипапов\ООБ	)	
	Prescription Use	(Per 21 CFTR 801	A109) /	T 445	

(Division Sign-Off)	
Division of Reproductive, A	bdominal,
and Radiological Devices	K070903
510(k) Number	1001010

	Mode of Operation									
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N <sub>.</sub>		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N .		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N.	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic	<u> </u>						. :			
Adult Cephalic										
Cardiac										
Transesophageal									: : '	
Transrectal									-: *: *:	
Transvaginal						-				
Transurethral						_				
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)										

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

(PLEASE DO	NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED
	concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 80), 109)
	Julivern
	(Division Sign-Off)
	Division of Reproductive, Abdominal,
	and Radiological Devices U171903

### **TEE022**

	Mode of Operation									
Clinical Application	А	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									<u> </u>	
Fetal		1		<del></del>				<u> </u>		
Abdominal								· ·	<u> </u>	· · · · · · · · · · · · · · · · · · ·
Intraoperative Abdominal									-	
Intraoperative Neurological		-						2		
Pediatric				ī.						
Small Organ (specify)										
Neonatal Cephalic		2								
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N[1]	N[2,3,4,6,8]
Transesophageal		N	N	N	N	N	N		N[1]	N[2,3,4,6,8]
Transrectal										
Transvaginal										
Transurethral										<u> </u>
Intravascular										
Peripheral Vascular										
Laparoscopic										<u> </u>
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

IJ	-	Applicable	combined	modes:	B+M+PW	+CW+CFM+	$^{ m PD}$

- [2] Tissue Enhancement Imaging (TEI)[3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE D	O NU	CORCU	E BELOW THIS I	LINE. CONTINUE ON ANOTHER P. Office of Device Evaluation (ODE)	AGE IF NEEDED	
		concu	Prescription U	se (Per 21 CFR 801.109)		
				Juliven		
		1		(Division Sign-Off)		•
				Division of Reproductive, A and Radiological Devices	bdominal,	2
				510(k) Number	KU1090	<u> </u>

### **TEE122**

	Mode of Operation									
Clinical Application	<b>A</b> :	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal					_					
Abdominal										·
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N(1)	N[2,3,5]
Small Organ (specify)				:					:	
Neonatal Cephalic										
Adult Cephalic										``
Cardiac	. : "	N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transesophageal		N	. N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transrectal										
Transvaginal						,				
Transurethral					-					
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)			:							

ı	Ц	Ap	plicab	ie com	bined	modes:	B+W+b/	V+CW+	-CFM-	+PD

- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM)
- [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NOT W ∞	RITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED
	Prescription Use (Per 21 CFR, 801, 199)
	(Division Sign-Off)
	Division of Reproductive, Abdominal,
	and Radiological Devices 117/19/13

### **IOE323**

		Mode of Operation									
Clinical Application	Α	В	. M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic				. *		-				<del></del>	
Fetal							<del></del>				
Abdominal		N	N	N		N	N	<del></del>	N(2)	N[3,4,5,6,8]	
Intraoperative Abdominal	<u> </u>	N	N	N		N	N		N(2)	N[3,4,6,8]	
Intraoperative Neurological						-					
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]	
Small Organ (specify) [1]		N	N	N		N	N .		N(2)	N[3,4,6,8]	
Neonatal Cephalic											
Adult Cephalic											
Cardiac	1										
Transesophageal											
Transrectal											
Transvaginal	1										
Transurethral				. "							
Intravascular											
Peripheral Vascular		N	N	N		N	N		N(2)	N[3,4,6]	
Laparoscopic									· · · · · · · · · · · · · · · · · · ·		
Muscolo-skeletal Conventional		N	N	N		N.	N		N(2)	N[3,4,6]	
Muscolo-skeletal Superficial		N	N	N	- 1. 1	N	N		N(2)	N[3,4,6]	
Other (Urological)									<del></del>		

ı	[1]	Small	l organs include	Thyroid,	Breast and	<b>Testicles</b>

- [2] Applicable combined modes: B+M+PW+CW+CFM+PD [3] Tissue Enhancement Imaging (TEI)

- [4] Compound Imaging
  [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

PLEASE DO NOT	concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)	
	dubteun	
	(Division Sign-Off)	
	Division of Reproductive, Abdominal,	
	and Radiological Devices 1/0/1/1972	~.
1.5	510(k) Number	21

						Mode of	Operation	··· <u> </u>		
Clinical Application	A	В	М	PWD (PW)	CMD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic							-			
Fetal		N	N	N		N	N		N[1]	N[2,3,4]
Abdominal			-							
Intraoperative Abdominal						_			· .	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)				7						
Neonatal Cephalic										
Adult Cephalic										
Cardiac								v .		
Transesophageal		1 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5								
Transrectal		N	N	N		N	N	1.00	N[1]	N[2,3,7]
Transvaginal		N	N	N		N	N		N[1]	N[2,3,7]
Transurethral										
Intravascular										
Peripheral Vascular					·					
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)		N	N	N	77.2	N	N		N[1]	N[2,3,5,7]

ĮΤ	Applicable	combined	modes:	B+M+	PW+CW+	CFM+PD

- [2] Tissue Enhancement Imaging (TEI)
- [3] Compound Imaging
- [4] Compass M-Mode (CMM) [5] VPAN
- [6] Tissue Velocity Mapping (TVM)
- [7] CnTI
- [8] XStrain
- [9] 3D/4D Imaging

(PLEASE DO NOT	WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED
	concurrence of CDRH, Office of Device Evaluation (4DM)
	Prescription Use (Per 21 CFR 801.109)
The second secon	

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number

### 2.0 CW Probe

	Mode of Operation										
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal										· · · · · · · · · · · · · · · · · · ·	
Intraoperative Abdominal											
Intraoperative Neurological							·			r.	
Pediatric											
Small Organ (specify)		,									
Neonatal Cephalic										<del></del>	
Adult Cephalic								4			
Cardiac				:	N						
Transesophageal			,								
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular					N						
Laparoscopic											
Muscolo-skeletal Conventional											
Muscolo-skeletal Superficial					:						
Other (Urological)	*.										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10] 3D/4D Imaging

	NTINUE ON ANOTHER PAGE IF NEEDED Device Evaluation (ODE)
Prescription Use (Per 2)	1 CFR 801.1091
	(Division Sign-Off) Division of Reproductive, Abdominal,

and Radiological Devices 207090 510(k) Number

### 5.0 CW Probe

						Mode of	Operation			
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal			٠.							·
Intraoperative Abdominal								· · · · · ·		
Intraoperative Neurological										
Pediatric										
Small Organ (specify)					:					-
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										.1
Transvaginal								·		<del></del>
Transurethral								:	·	
Intravascular										
Peripheral Vascular					N					<del></del>
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										er er er
Other (Urological)						1				

N= new indication; P≖ previously cleared by FDA; E= added under Appendix E

- [1] Small organs include Thyroid, Breast and Testicles.
- [2] Applicable combined modes: B+M+PW+CW+CFM+PD
- [3] Tissue Enhancement Imaging (TEI)
- [4] Compound Imaging
- [5] Compass M-Mode (CMM)
- [6] VPAN
- [7] Tissue Velocity Mapping (TVM)
- [8] CnTI
- [9] XStrain
- [10]

3D/4D Imaging		
(PLEASE DO NOT	WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED	
	concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)	
	galiter	
	(Division SignVOff)	
	Division of Reproductive, Abdominal,	

and Radiological Devices 510(k) Number \_\_\_\_

The following section is page numbered independently from the remainder of the submission.

4070903

Clearance Method	Cleared via K040596	Cleared via K050326 & Memorandum to File referencing K040596	Cleared via K040596	Cleared via K050326 & Memorandum to File referencing K040596	Cleared via K043588 & 040596	Cleared via K050326 & Memorandum to File referencing K040596	Cleared via Memorandum to File referencing K040596	Cleared via K040596
Indications for Use	Abdominal, Adult Cephalic, Cardiac	Abdominal, Cardiac, Peripheral Vascular	Pediatric, Neonatal Cephalic, Cardiac, Perinheral Vascular	Pediatric, Neonatal Cephalic, Cardiac, Peripheral Vascular	Abdominal, Neonatal Cephalic, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Abdominal, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Abdominal, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Fetal, Abdominal, Pediatric, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological
Type	Phased Array	Phased Array	Phased Array	Phased Array	Linear Array	Linear Array	Linear Array	Convex Array
Probe	PA230E	PA121E	PA122E	PA023E	LA523	LA522E	LA435	CA421

Probe	Type	Indications for Use	Clearance Method
LA532E	Linear Array	Abdominal, Small organ, Pediatric. Perioheral	Cleared via K050326 & Memorandum to File referencing K040596
		Vascular, Musculoskeletal	
		Conventional & Superficial	
CA430E	Convex Array	Fetal, Abdominal, Small	Cleared via K050326 & Memorandum to
		organ, Peripheral Vascular,	File referencing K040596
		Musculoskeletal	
		Conventional &	
		Superficial, Urological	
LA424	Linear Array	Abdominal, Small organ,	Cleared via K050326 and Memorandum to
		Pediatric, Peripheral	File referencing K040596
		Vascular, Musculoskeletal	
		Conventional & Superficial	
TEE022	Linear Array	Cardiac, Transesophageal	Cleared via K040596
TEE122	Linear Array	Pediatric	Via this submission
		Cardiac, Transesophageal	Cleared via Memorandum to File
·-			referencing K040596
IOE323	Convex Array	Abdominal	Cleared via K052805 & K061755
		Intraoperative Abdominal,	
		Small organ, Pediatric,	
		Peripheral Vascular,	
		Musculoskeletal	
		Conventional & Superficial	

Probe	Type	Indications for Use	Clearance Method
EC123	Linear Array	Fetal, Urological, Transrectal, Transvaginal	Cleared via K040596
BS230	Phased Array	Abdominal, Adult Cephalic, Cardiac	Cleared via K060827
BC431	Convex Array	Fetal, Abdominal, Pediatric, Peripheral Vascular, Urological	Cleared via K060827
2.0 CW	Doppler Array	Cardiac, Peripheral Vascular	Cleared via K052805 Via this submission
5.0 CW	Doppler Array	Cardiac, Peripheral Vascular	Via this submission Cleared via K052805

Biopsy	Type	Indications for Use	Clearance Method
Attachments			
ABS421	Biopsy attachment	CA421, CA430E &	Cleared via K053154 and via this
		CA431- Fetal, Abdominal,	submission
		Small organ, Peripheral	
		Vascular, Musculoskeletal	
		Conventional &	
		Superficial, Urological	
ABS621	Biopsy attachment	CA621 & CA631 - Fetal,	Cleared via K053154 and via this
		Abdominal, Pediatric,	submission
		Small organ, Peripheral	
		Vascular, Musculoskeletal	
		Conventional &	
		Superficial, Urological	
ABS523	Biopsy attachment	LA523, LA522E &	Cleared via K053154 and via this
		LA532E - Abdominal,	submission
		Small organ, Peripheral	
		Vascular, Pediatric,	
		Musculoskeletal	
		Conventional & Superficial	
ABS424	Biopsy attachment	LA424 & LA435-	Cleared via K053154 and via this
		Abdominal, Small organ,	submission
		Pediatric, Peripheral	
		Vascular, Musculoskeletal	
	2.00	Conventional & Superficial	
ABS123	Biopsy attachment	EC123 - Fetal, Urology,	Cleared via K040596
		Transrectal, Transvaginal	

Biopsy	Type	Indications for Use   Clearance Method	Clearance Method
Attachments			
BS230 Kit	Biopsy attachment	BS230 - Abdominal, Adult Cleared via K060827 Cephalic, Cardiac	Cleared via K060827
ABS15	Biopsy attachment	IOE323 - Abdominal,	Cleared via K052805
		Small organ, Pediatric,	
		Peripheral Vascular,	
		Musculoskeletal	
		Conventional & Superficial	